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FEDERAL WAY, WA 98063		1651		

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Please find below and/or attached an Office communication concerning this application or proceeding.

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/680,676 Filing Date: October 07, 2003

Appellant(s): TOLAND, MITCHELL R.

Teresa Wiant For Appellant

**EXAMINER'S ANSWER** 

Application/Control Number: 10/680,676

Art Unit: 1651

This is in response to the appeal brief filed 3/2/2006 appealing from the Office action

Page 2

mailed 6/20/2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the

brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings

known to the examiner which may be related to, directly affect or be directly affected by

or have a bearing on the Board's decision in the pending appeal:

Appeal briefs have been filed in two related cases to this application: 09/700037

& 10/680675.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

Application/Control Number: 10/680,676

Art Unit: 1651

Page 3

The summary of claimed subject matter contained in the brief is correct.

## (6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct with the exception that the examiner hereby withdraws the prior art rejection in view of applicant's arguments.

### (7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

### (8) Evidence Relied Upon

The prior art rejection has been withdrawn so no evidence is being relied upon.

# (9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

#### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 stand finally rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Further, the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claims (in the parent 09/700037) were originally drawn to a method of classifying plant embryos according to their "quality." The majority of specification discusses the "quality" of the embryos but also describes how certain "quantifiable characteristics" are indicative of quality, e.g. germination potential and desiccation tolerance. The only real utility that plant embryos (zygotic or somatic) have is to germinate into plants. Any measure of quality or the "quantifiable characteristics thereof" begins and ends with the ability of the embryo to germinate. Any other "quantifiable characteristics" of quality are simply subsets of germination potential, e.g. temperature or moisture tolerance. As such, applicant's claims have always been interpreted by the examiner to be classifying embryos according to at least their ability to germinate into plants.

Appellant has not, in the specification as originally filed, shown possession of the claimed invention nor taught how to make and use said invention. The examiner

understands that the appellant has developed a classification model using the raw digital image data compiled by digital image analysis of embryos of a known quantifiable characteristic. Appellant has demonstrated that one can take embryos which are visually determined to be good (an old and well known process), capture digital image data, and then take that data and apply well known data processing algorithms to interpret the data and produce a "classification model." It is not in the creation of a such a model that appellant has failed to adequately describe or enable in their claimed invention but in the application of said model. As such, the invention as a whole has not been adequately described or enabled.

The examiner recognizes applicant does have enablement and description for wherein the raw digital image produces data to quantify the morphology of an embryo so that embryos are selected which have a known advantageous morphology. Using morphology as a basis for selecting embryos is old and well known- embryos of a certain morphology tend to germinate better than others. It is not adequately described in the specification how one could practice this invention wherein a digital image of only "any portion thereof" is captured and a model is made. It would appear that applicant's image model is dependent on an analysis of the morphology of the embryos and one could not practically and properly determine the morphology of the embryo in questions using only "any portion thereof" the embryo.

Appellant is intending to show possession for generic claims to "quantifiable characteristics" however the specification does not contain an adequate description for

the entire scope of this phrase and thus the claims. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. In the instant case, the raw digital image classification model may be a usable to select embryos of a certain morphology but not for all the "quantifiable characteristics" Appellant is alleging. Appellant has not shown anything to indicate that the limitations of claim 14 can be "selected for" using a raw digital image classification model. It is not clear how one could determine if an embryo is pathogen resistant by analyzing a digital image. The specification appears to be speculative in the ability to use digital image data to classify/select an embryo with any or all of the claimed properties. All of applicant's data and examples discuss only the correlation between "quality" and morphology there is nothing to convey to one of skill in the art that the properties in claim 14 could be reasonably predicted using a digital image classification model.

Absent an actual reduction to practice, appellant can still show possession of an invention but applicant has not done so. MPEP 2163 states: Possession may be shown in many ways. For example, possession may be shown by describing an actual

reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"); see also Pfaff v. Wells Electronics, Inc., 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646 ("The word invention' must refer to a concept that is complete, rather than merely one that is substantially complete."

Appellant has not described the invention in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention absent any reduction to practice. Appellant's invention requires that one can assign a "quantifiable characteristic" of quality to an unknown embryo however the specification does not describe that one can actually do that. Appellant has not shown that they possessed a method for properly and practically classifying somatic embryos using a digital image data classification model.

It follows logically that the entire claimed invention has not been enabled by the instant specification because applicant has not taught how to apply the instant invention such that one of skill in the art could predict using applicant's classification model that whether or not any embryo would germinate or have one of the other "characteristics" as in claim 14. The specification has not enabled the use of "any portion thereof" an embryo as the means for creating a classification model and has not enabled the use of the digital image classification model to classify/select embryos for all alleged "quantifiable characteristics," e.g. pathogen resistance.

It would require undue experimentation to practice the claimed invention at the claimed scope. Appellant's invention requires a classification of an embryo based on morphology as no other image data produced would appear to be meaningful if the morphology is not quantified. Using only "any portion thereof" an embryo does not tell its morphology and thus the data collected could not be used to properly classify an embryo based on its quantifiable characteristics of quality. Furthermore, as there appears to be no specific correlation between morphology and all of applicant's other "quantifiable characteristics" of quality, e.g. pathogen resistance, one could not practice this invention at its claimed scope. The use of the instant method to determine that, for example, a particular embryo is pathogen resistant is simply not supported by any working examples or explained in any way which would overcome the lack of working examples. Nothing in the specification supports the allegation that embryos can be

classified by "quantifiable characteristics" other than morphology using a digital image classification model.

#### (10) Response to Argument

The examiner recognizes that the instant method is enabled and adequately described wherein the claimed invention reads on using digital image data to create a classification model and selecting embryos based on their morphology. The rejection has been pared down to focus on which parts of the claimed invention are beyond that scope or are generic to the specific adequately described and enabled invention. Appellant argues that the examiner's rejection is in error because the claimed invention does not require a direct comparison of the digital image data of embryos but uses a classification model. The examiner recognizes that the classification model is not a one point direct comparison such as Appellant's length X analogy, but the instant method does use a direct comparison between two embryos. One embryo (the known) yields digital image data which is applied to an algorithm to yield the classification model and then the model is used to classify the raw spectral data of an unknown embryo. While the comparison is not as simple as "if a plant embryo has length X, then it is likely to germinate," it is still a comparison of the digital image data produced by one embryo to another. Appellant's claimed invention requires a proper classification of an

embryo using the classification model developed using another embryo and appellant has not shown that that can be done to the entire scope of the claims.

Appellant did not show possession of (nor enable) a method for effectively classifying unknown plant embryos using a digital image classification model which is not based on morphology. Even when based on morphology, Appellant did not show possession of (nor enable) a method for effectively classifying unknown plant embryos using a digital image classification model based to select for quantifiable characteristics such as pathogen resistance.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

e Lankford Examiner

AU 1651<sup>l</sup>

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